

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED STATES OF AMERICA,

Plaintiff,

V.

C.A. No. 20-1744-CFC

WALMART INC. AND WAL-MART
STORES EAST, LP,

Defendants.

**DEFENDANTS' MOTION TO STAY
PENDING THE SUPREME COURT'S DECISIONS IN *RUAN* AND *KAHN***

In Counts I and II of its Complaint, the Government seeks to hold Defendants Walmart Inc. and Wal-Mart Stores East, LP (collectively, “Walmart”) liable for civil penalties because Walmart’s pharmacists allegedly departed from the “usual course” of pharmacy practice when dispensing controlled substances and allegedly “knowingly” filled invalid prescriptions. D.I. 1, ¶¶ 698, 703. On November 5, 2021, the Supreme Court granted certiorari in two cases, *Ruan v. United States*, __ S. Ct. __, 2021 WL 5148067 (U.S. Nov. 5, 2021) (mem.), and *Kahn v. United States*, __ S. Ct. __, 2021 WL 5148069 (U.S. Nov. 5, 2021) (mem.), that could significantly affect the resolution of those Counts. In *Ruan* and *Kahn*, the Supreme Court will address what it means for a *prescriber* to depart from the usual course of *medical* practice in writing prescriptions; the answer to that question will shed considerable light on what it means for a *pharmacist* to depart from the usual course of *pharmacy* practice when filling them. The Supreme Court will also consider the circumstances under which a registered prescriber’s prescriptions are invalid; the Supreme Court’s description of those circumstances will likely affect how pharmacists may be held liable for *knowingly* filling invalid prescriptions.

Given this significant overlap, the Supreme Court’s grant of certiorari in *Ruan* and *Kahn* warrants a limited stay of this litigation—at most until June 2022, the end of the Supreme Court’s current Term. A short stay would conserve this Court’s resources, giving it the benefit of the Supreme Court’s forthcoming guidance before

it issues a decision, and will not prejudice the Government. Walmart therefore respectfully asks the Court to stay this litigation pending the Supreme Court's decisions in *Ruan* and *Khan*.

STATEMENT OF FACTS AND STAGE OF THE PROCEEDINGS

1. On December 22, 2020, the United States sued Walmart in this Court. *See* D.I. 1. Count I seeks civil penalties pursuant to 21 U.S.C. § 842(a)(1) and 21 U.S.C. § 829 based on Walmart's alleged violations of 21 C.F.R. § 1306.04(a). *See id.* ¶¶ 697–701. That regulation provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment ... is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

The Government alleges that Walmart violated this regulation when its pharmacists filled prescriptions that “Walmart knew” “were not issued for a legitimate medical purpose, or were not issued in the usual course of professional medical practice, or both.” *Id.* ¶ 107.

Count II of the Complaint purports to seek civil penalties pursuant to 21 U.S.C. § 842(a)(1) and 21 U.S.C. § 829 based on alleged violations of 21 C.F.R. § 1306.06. *See id.* ¶¶ 702–06. That regulation provides:

A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.

The Government alleges that Walmart violated this regulation every time one of its pharmacists allegedly failed to follow “professional pharmacy practice standards,” such as the alleged duties to identify red flags in problematic prescriptions, resolve those red flags before filling the prescriptions, and then document those resolutions in writing. *Id.* ¶ 112.*

Walmart moved to dismiss the Government’s Complaint. *See* D.I. 26. This Court set oral argument on Walmart’s motion for November 22, 2021. *See* Oral Order (Oct. 19, 2021).

2. On November 5, 2021, the Supreme Court granted certiorari in *Ruan* and *Kahn*. Both cases arise from criminal convictions of doctors registered to prescribe controlled substances. Section 841(a)(1) of the CSA makes it unlawful to knowingly or intentionally distribute controlled substances “[e]xcept as authorized”

* Along with these dispensing-related counts, the Government also seeks to hold Walmart liable on a distinct, distribution-related Count III for conduct that occurred when Walmart self-distributed controlled substances to its own pharmacies. *See* D.I. 1, ¶¶ 707–10.

by that statute. In *United States v. Moore*, the Supreme Court held that physicians could be prosecuted under this provision “when their activities fall outside the usual course of professional practice.” 423 U.S. 122, 124 (1975).

Ruan and *Kahn* will consider issues that have arisen under *Moore* and 21 C.F.R. § 1306.04(a), the regulation that tracks *Moore*’s requirements when defining what counts as a valid prescription. In *Ruan*, the Court will address “whether a physician alleged to have prescribed controlled substances outside the usual course of professional practice may be convicted under Section 841(a)(1) without regard to whether, in good faith, he ‘reasonably believed’ or ‘subjectively intended’ that his prescriptions fall within that course of professional practice.” Pet. at i, *Ruan v. United States*, No. 20-1410 (U.S. Apr. 5, 2021). In *Kahn*, the Supreme Court will consider similar questions, as well as a distinct one: whether “the ‘usual course of professional practice’ and ‘legitimate medical purposes’ prongs of [21] C.F.R. § 1306.04(a) [should] be read in the conjunctive or the disjunctive.” Pet. at 1, *Kahn v. United States*, No. 21-5261 (U.S. July 26, 2021). Because the Supreme Court granted certiorari early in its October Term 2021, the cases should be decided (at the latest) by the end of June 2022.

ARGUMENT

I. A STAY WILL CONSERVE JUDICIAL RESOURCES WITHOUT MATERIALLY SLOWING THESE PROCEEDINGS OR HARMING THE GOVERNMENT.

Whether to stay litigation “is a matter left to the Court’s discretion.” *Amgen Inc. v. Hospira, Inc.*, No. 20-cv-0561, 2021 WL 65065, at *1 (D. Del. Jan. 7, 2021) (Connolly, C.J.). In exercising that discretion, this Court considers “whether a stay will simplify the issues and trial of the case,” “whether discovery is complete and a trial date has been set,” and “whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party.” *Id.* Each factor supports a stay here.

A. *Ruan and Kahn* Will Significantly Affect Counts I and II.

The Supreme Court’s forthcoming decisions will materially affect this litigation. That is perhaps most obvious with respect to Count II. As the briefing on Walmart’s motion to dismiss shows, the parties vigorously disagree about what it means for a pharmacist to depart from the “usual course of [pharmacy] practice” for purposes of 21 C.F.R. § 1306.06. On the Government’s view, pharmacists violate this provision every time they depart from “the profession’s generally accepted practices,” D.I. 42 at 20 (internal quotation marks and citation omitted), while on Walmart’s they do so only when they have stopped acting as professional pharmacists “*at all*,” D.I. 47 at 10 (internal quotation marks and citation omitted).

In *Ruan* and *Kahn*, the Supreme Court will address what it means for a prescriber to depart from the “usual course of [medical] practice” in violation of 21 C.F.R. § 1306.04(a) (and the Supreme Court’s gloss on the CSA in *Moore*) when writing prescriptions. See Pet., *Ruan*, *supra*, at i; Petition, *Kahn*, *supra*, at 1. Although *Ruan* and *Kahn* are criminal cases, the Supreme Court’s discussion will almost certainly shed light on what it means for a pharmacist to depart from the “usual course” of pharmacy practice in violation of 21 C.F.R. § 1306.06. After all, these neighboring provisions both address similar conduct by licensed professionals through identical language (“acting in the usual course of his professional practice”). Because *Ruan* and *Kahn* will likely affect this Court’s resolution of Count II, a stay is warranted. See, e.g., *Amgen*, 2021 WL 65065, at *2 (granting stay because of “overlapping invalidity and noninfringement issues” between two pieces of litigation); *f’real Foods, LLC v. Welbilt, Inc.*, No. 19-cv-1028, 2019 WL 5626857, at *2 (D. Del. Oct. 31, 2019) (Connolly, C.J.) (similar); *Advanced Micro Devices, Inc. v. MediaTek, Inc.*, No. 19-cv-70, 2019 WL 4082836, at *2 (D. Del. Aug. 29, 2019) (granting stay where other ongoing litigation would “address[] directly issues concerning” one patent and would “perhaps indirectly” address another patent).

Ruan and *Kahn* will also affect Count I, which accuses Walmart’s pharmacists of knowingly filling invalid prescriptions in violation of 21 C.F.R. § 1306.04(a). *Ruan* and *Kahn* will likely set the bounds of what qualifies as an invalid prescription

for purposes of that regulation. Both petitions ask the Court to hold that a prescriber cannot leave the bounds of acceptable practice unless he knowingly or intentionally does so, or to hold that a subjective good-faith belief in the legitimacy of the prescription defeats liability. *See* Pet., *Ruan, supra*, at i; Pet., *Kahn, supra*, at 1. If the Supreme Court agrees, then the Government here must allege (which it has not) and later prove that Walmart’s pharmacists *knew* that prescribing doctors lacked a *subjective* good-faith belief in the validity of their chosen treatments. Similarly, in *Kahn*, the Court will decide whether the Government must prove both that the prescriber departed from his “usual course of professional practice” and that the prescription lacked any “legitimate medical purpose.” If so, then the Government’s theory—that Walmart may be held liable any time a pharmacist knowingly filled a prescription that was “not issued for a legitimate medical purpose[] *or w[as]* not issued in the usual course of professional medical practice,” D.I. 1, ¶ 107 (emphasis added)—is mistaken.

To be sure, Walmart’s pending motion to dismiss provides reasons to end this litigation that do not turn on what the Supreme Court might say in *Ruan* and *Kahn*. *See, e.g.*, D.I. 27 at 5–17 (explaining why the Government has not adequately alleged scienter); *id.* at 19–23 (explaining why the Government cannot recover civil penalties for its alleged violations of 21 C.F.R. § 1306.06); *id.* at 28–32 (explaining why the Government’s distribution-related claim fails). But some of Walmart’s

motion-to-dismiss arguments *will* be impacted by *Ruan* and *Kahn*, and there is no reason for this Court to engage in piecemeal adjudication, first reviewing Walmart’s motion to dismiss under present law and then considering that motion again (if necessary) in light of *Ruan* and *Kahn*.

Although the Government’s distribution-related count will not be affected by the decisions in *Ruan* and *Kahn*, the issues between two pieces of litigation need not overlap entirely to justify staying one in favor of the other. *See, e.g., Advanced Micro Devices*, 2019 WL 4082836, at *2. And it makes sense for this Court to resolve Walmart’s entire motion to dismiss in one swoop, with everything (including *Ruan* and *Kahn*) in hand. A single decision on the motion to dismiss will allow the parties to make informed, efficient decisions about case management and discovery issues that cross over any claims that may survive.

B. The Early Stage of This Litigation Supports a Stay.

A stay in light of other pending litigation is particularly appropriate when the litigation to be stayed is in its relative infancy. *See, e.g., Amgen*, 2021 WL 65065, at *2 (granting stay in part because the parties “ha[d] not held a Rule 26(f) conference,” had not “scheduled [a] Rule 16(b) conference,” had “yet to initiate fact discovery,” and had not set a “trial date”); *f’real Foods*, 2019 WL 5626857, at *2 (granting stay in part because “discovery ... ha[d] barely begun,” whereas the other litigation was well underway); *Advanced Micro Devices*, 2019 WL 4082836, at *2

(granting stay in part because “[d]iscovery ha[d] not begun, a trial date ha[d] not been set, and there [wa]s no scheduling order in place”).

Such is the case here. Walmart’s motion to dismiss has been briefed but not yet argued, much less decided. Given that pending motion, the parties have not held a Rule 26(f) conference or otherwise started fact discovery, let alone set a trial date. By contrast, *Ruan* and *Kahn* will be fully briefed over the next few months, and the Supreme Court will issue its binding decisions by June 2022 at the latest. It will not take long to receive the Supreme Court’s directly on-point guidance that could limit or eliminate some of the Government’s theories of Walmart’s liability.

C. The Government Will Not Be Harmed by a Short Stay.

Finally, pausing this litigation for a few months while the Supreme Court resolves *Ruan* and *Kahn* will not prejudice the Government. The Government primarily seeks civil penalties through this litigation. If available, however, those penalties can be recovered just as easily seven months from now as today. The Government also technically requests injunctive relief, but it cannot claim any exigency on that score, as it has not sought any immediate remedy such as a temporary restraining order or a preliminary injunction.

Moreover, the Government can hardly be heard to complain about a short delay. It has known about its possible claims against Walmart for years. Yet it only sued in December 2020—and even then only *after* Walmart filed its own declaratory

judgment action seeking to clarify its obligations under the CSA. *See, e.g., Advanced Micro Devices*, 2019 WL 4082836, at *2 (granting stay in part because the opposing side waited until two years after the parallel litigation to file its own suit). Given that context, there is no reason to believe that waiting for the Supreme Court’s ruling would cause the Government any harm at all, let alone the kind of “irreparable harm” that this Court has looked for when assessing the propriety of a stay in light of related litigation. *See id.*; *see also, e.g., Amgen*, 2021 WL 65065, at *2 (granting stay despite possible delay of “several years” because the opposing side could still secure monetary damages and would not be hurt by the absence of injunctive relief in the interim).

Pressing ahead without the Supreme Court’s guidance in *Ruan* and *Kahn* would risk wasting the Court’s resources with no offsetting gains to judicial economy or overarching fairness. Those are precisely the circumstances in which a stay is warranted.

CONCLUSION

For these reasons, the Court should stay this litigation pending the Supreme Court’s decisions in *Ruan* and *Kahn*.

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Dated: November 9, 2021